

REMARKS

I. Status

Claims 1-13 are pending in the application.

Claim 1 is currently amended to further clarify the subject matter for which protection is sought, as discussed in greater detail below. Claims 2, 3 and 13 have been deleted. All amendments and claim deletions herein are being made without prejudice to pursuing such subject matter in any continuing application, e.g., a continuation, divisional, request for continuation, etc. Support for the amendments can be found throughout the specification. No new matter is being added by the current amendments.

Claims 1-13 stand rejected under 35 USC §112, ¶1 with regard to written description. Claims 1-5, 7-8, 11 and 13 stand rejected under 35 USC §102(b) over U.S. Patent No. 5,714,159. Claims 1-3, 6, 9-10 12-13 stand rejected under 35 USC § 103(a) over U.S. Patent Nos. 5,714,159 and 6,232,304. Applicants traverse the foregoing rejections.

II. Amended Claims 1-4, 6-8 and 11-15 Comply With the Written Description Requirements of §112, ¶1

The standard for written description is whether a person skilled in the art would have recognized that the inventor was in possession of the invention as claimed at the time the application was filed.

While acknowledging with regard to the bioactive agent that Applicants have possession of the aryl-heterocyclic compounds described in U.S. 4,831,031, the Examiner argues that the specification is sufficient to show possession of all bioactive agents or all aryl-heterocyclic compounds.

Contrary to the Examiner's contention, the instant specification does teach the characteristics of bioactive agents sufficiently to indicate Applicants' possession of the invention. The specification describes preferred bioactive agents as being basic, including for example those that are amine-containing. Examples provided of such basic bioactive amines include simple organic compounds having a molecular weight of more than 150 Da, peptides comprising at least two amino-acids and proteins (see, page 3, lines 4-9). Therefore, Applicants had possession of the claimed invention at the time the application was filed.

Nevertheless, to facilitate the allowance of the present application, Applicants are filing amendments to claim 1 to further define the invention based on the written description provided in the specification. Claim 1 now provides that bioactive agents are basic. Support for the amendments can be found throughout the specification, including at page 15, lines 7-9.

Based on the amendments to claims 1 and the arguments presented above, Applicants request reconsideration and withdraw of this rejection.

IV. Amended Claims 1-5, 7-8, 11 and 13 Are not Anticipated Under §102 By Shalaby

Claims 1-5, 7-8, 11 and 13 stand rejected under §102(b) U.S. Patent 5,714,159 to Shalaby. Applicants submit that as amended, the claims are not anticipated by Shalaby.

Shalaby makes reference to the carboxylation of end-groups of a copolymer designated Component A (col. 10, lines 2-4). Applicants submit that unlike in Shalaby, the claims as amended are directed to a liquid conjugate wherein the polymer is selected from a polycarbonate, a polyester-carbonate and a polyester carrying two or more carboxyl groups situated in medial portions off the polymer. Applicants wish to point out that in Examples 1 and 3 of the their specification that illustrates the present invention, malic and citric acid are used as initiators providing 2-3 carboxylic groups per chain. Furthermore, Applicants wish to point out that the polymers of Example 5 (i.e., the O-polymer) also have 2 groups most of which are within the medial portion of the chains rather than on their ends.

Shalaby does not disclose a liquid conjugate comprising a basic bioactive agent and an absorbable liquid polymer selected from a polycarbonate, a polyester-carbonate and a polyester carrying two or more carboxyl groups situated in medial portions off the polymer. The polymers referred to in Shalaby do not have carboxylic groups on medial portions of the polymer but only on the ends. Therefore, Shalaby fails to disclose the polymer as claimed in the present invention.

Based on the amendments to the claims Applicants request reconsideration and withdraw of this rejection.

V. Amended Claims 1-3, 6, 9-10 and 12-13 are not Obvious over Shalaby and Kim

Claims 1-3, 6, 9-10 and 12-13 stand rejected under §103(a) over Shalaby and U.S. Patent 6,232,304 to Kim. Applicants traverse the rejection.

Amended claim 1 from which all other claims depend is generally directed to liquid conjugates comprising a basic bioactive agent and an absorbable liquid polymer.

Kim is directed to compositions of matter comprising a pharmaceutically acceptable salt of an aryl-heterocyclic compound such as ziprasidone in a cyclodextrin.

Shalaby is directed to Hydrogel-forming, self-solvating absorbable polyester copolymers.

Applicants submit, however, that no motivation exists to combine Kim and Shalaby in order to reach the present invention.

The Examiner bears the burden of establishing a prima facie case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (CAFC 1993).

It is error for the Examiner to reject a claimed invention as an obvious combination of the teachings of multiple prior art references when the prior art provided no teaching, suggestion or incentive supporting the combination. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (CAFC 1990).

The Supreme Court recently reaffirmed its own earlier admonition against the dangers of hindsight bias stated in *Graham v. John Deere*, 383 US 1, 148 USPQ 459 (1966) to avoid the "temptation of reading into the prior art the teachings of the invention in issue". *KSR Int'l Co. v. Teleflex, Inc.*, 550 US 1, at 17 (2007).

The Supreme Court has described requirements for the possible applicability of an "obvious to try" test in determining whether a combination renders an invention obvious:

When there is a design need or market pressure to solve a problem *and there are a finite number of identified predictable solutions*, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp...[T]he fact that a combination was obvious to try might show that it was obvious under §103. *KSR* at 17 (emphasis added).

The inventors in Kim addressed the problem of poor solubility of ziprasidone.

The disclosure in Shalaby solves a very different problem. Shalaby seeks to create absorbable hydrogel forming copolymers which do not require the use of solvents, are compliant, swollen, mechanically compatible gels which adhere to surrounding tissue..

The problems that are sought to be solved in Kim and Shalaby are so different, and their methodologies so unrelated to each other that common sense requires they would not have been combined by one with ordinary skill in the art.

Applicants submit that the Examiner has failed to provide any teaching, suggestion or motivation in the prior art to support a combination of the relevant disclosure in the cited references. The Examiner has also failed to show how the cited references, either individually or in combination with each other, would motivate one of ordinary skill in the art to practice the invention. Furthermore, given the infinite number of possible solutions for solving the problem of poorly soluble drug compounds, it would be error and is beyond common sense to expect that practitioners with ordinary skill in the art would be motivated to combine the Shalaby and Kim references.

Based on the amendments to the claims and the arguments presented above, Applicants request reconsideration and withdraw of this rejection.

VI. **Conclusion**

Having addressed all outstanding issues, Applicants kindly request removal of all rejections and allowance of the claim as amended. To the extent the Examiner believes it would facilitate allowance of this case, the Examiner is urged to call the undersigned at the number below.

Applicants believe a fee is associated with the present filing, which is detailed in form PTO/SB/17 filed herewith. To the extent any additional fee is due, the Commissioner is hereby authorized by this paper to charge any required fees or credit any overpayment to Deposit Account 161445.

Respectfully submitted,

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